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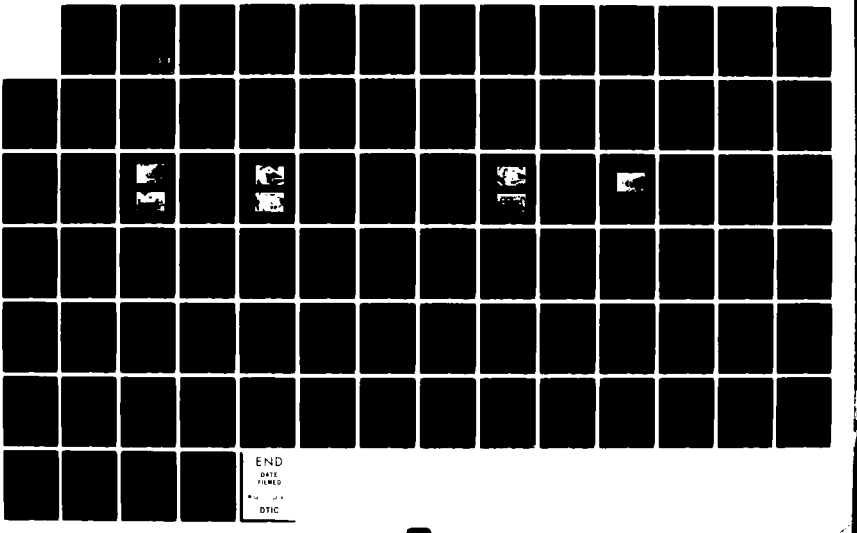

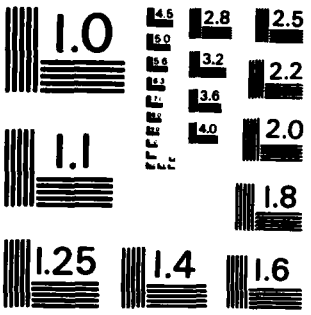

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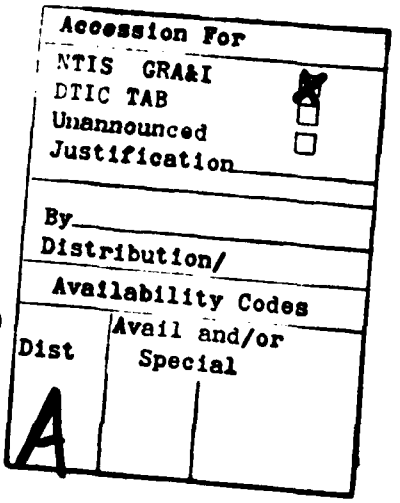
EVALUATION OF A GLASS IONOMER RESTORATION TO TREAT HYPERSENSITIVE CERVICAL ANATOMIC DEFICIENCIES

by

Edward B. Mandel, D.D.S.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Restorative Dentistry (Operative) at the Horace H. Rackham School of Graduate Studies of The University of Michigan Ann Arbor, Michigan

March 1983



Thesis Committee Members:

Professor Gerald T. Charbeneau, Chairman
Professor Major M. Ash, Jr.
Associate Professor Ronald J. Heys

DEDICATION

To my wife Della, for her love, encouragement, and patience during the course of my graduate studies, and for creating a little bit of heaven in our home.

To my children David and Rachel, for loving their Dad and understanding when I had to study and could not always play with them.

To my parents Bernard and Shirley Mandel, for their love, support, and guidance during my personal and professional development.

To my parents-in-law Jerome and Muriel Chasan, for their love and encouragement.

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INTRODUCTION

Hypersensitivity of exposed coronal or radicular dentin can be a distressing problem to a patient. When this occurs in an area of cervical abrasion or erosion the problem is compounded by presenting the dentist with a difficult restorative situation. The use of traditional restorative materials such as amalgam or cohesive gold requires tooth preparation to provide mechanical retention which may increase the sensitivity or further weaken the tooth. The use of acid-etch resins in these lesions without mechanical retention has been largely unsuccessful as these materials bond poorly to dentin. Restoration may also be carried out by the use of a glass ionomer cement restoration. This material bonds to tooth structure-dentin as well as enamel, and therefore may not require any mechanical tooth preparation. The material may also be anticariogenic as it leaches fluoride ions into the surrounding tooth structure.

If the mechanism of dentinal sensitivity involves a hydrodynamic effect on the dentinal fluid acting through patent dentinal tubules, then the application of a restoration may block these tubules and reduce or eliminate the sensitivity. The only published study of a glass ionomer to treat sensitive cervical anatomic deficiencies evaluated the sensitivity with only an overall subjective rating scale. The present

study differs in that the sensitivity will be rated upon the application of specific, calibrated stimuli to the lesions both before and after the glass ionomer restorations are placed. The objective of the research will be to test the usefulness of a glass ionomer cement to treat hypersensitive cervical anatomic deficiencies with a restorative material that requires no tooth preparation for its application.

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REVIEW OF THE LITERATURE

Abrasion / Erosion

Pindborg[1] defines abrasion as the pathologic wearing away of dental hard tissue by the friction of a foreign body independent of occlusion. He defines erosion as a superficial loss of dental hard tissue by a chemical process which does not involve bacteria.

The incidence of cervical tissue loss has been studied and reported by many investigators. Kitchin[2], in a study of two hundred patients, reported that over 75 percent of them age forty or older had some degree of cervical abrasion with 42 percent having defects deeper than 0.5 mm. In a random sample of over 10,000 extracted teeth, Sognnaes, Wolcott, and Xhonga[3] found that 18 percent had some degree of cervical erosion with a somewhat higher frequency for mandibular teeth. Zipkin and McClure[4] noted that 32 percent of their patients age forty or above had cervical erosion with a greater prevalence for maxillary teeth and an approximately equal degree of tissue loss on both sides. Radentz, Barnes, and Cutright[5] reported that 50 percent of patients in their study with an age range of seventeen to forty five had some degree of cervical abrasion with a greater tissue loss on the maxillary teeth. They found maxillary first molars and first premolars most severely affected, but

did note that the highest percentage of abrasion areas were in the maxillary right quadrant. Brady and Woody[6] described cervical abrasion lesions as being of two distinct types: a more common (68%) angular and deep lesion and a less common (32%) rounded and shallow lesion. Hollinger and Moore[7] found cervical defects most frequently on cuspids and premolars with the angular lesions four times as common as rounded lesions.

The etiology of cervical hard tissue loss has long been a subject of controversy. In 1902, Kirk[8] suggested that the cause was an acidic mucous produced by altered buccal mucous glands. Miller[9] in 1907 concluded that most cases of loss of tooth structure were by mechanical action, especially the action of the toothbrush and tooth powder. Other early reports claim a disorder of protein metabolism[10] or an acidic exudate from the gingival crevice[11] as the primary etiologic factor in cervical anatomic deficiencies. Kornfeld[12] believed that occlusal irregularities contributed to cervical tissue loss, whereas Rost and Brodie[13] concluded that a hyperactivity of soft tissues in contact with cervical areas caused these lesions by means of an abrasive action.

The controversy over the etiology of cervical tissue loss revolves around the relative importance of mechanical and chemical factors. Stafne and Lovestedt[14] discussed the contribution of chemical erosion to cervical tissue loss, especially as caused by acid fruits or candies. Most investigators, however, believe that the primary etiologic factor in angular, notch-like lesions in the gingival third of a tooth is a mechanical abrasion related to toothbrushing. Kitchin[2] reported that teeth in areas of good oral hygiene had about twice the abrasion as teeth in areas of poor oral hygiene. In an in vitro study, Manly and Foster[15]

concluded that the force of toothbrushing was highly significant as a factor in cervical abrasion. In separate clinical studies, Radentz, Barnes, and Cutright[5] and Hollinger and Moore[7] concluded that cervical abrasion was related to factors associated with the initial stages of toothbrushing such as use of large quantities of dentifrice, the areas first brushed by the patient, and excessive brushing pressure. Indeed, both Arnim and Blackburn[16] and Meister, Braun, and Gerstein[17] offer case reports which document the abrasive destruction of teeth related to excessive brushing force with large amounts of dentifrice.

Microscopically, Tronstad[18] reported that exposure of dentin by attrition led to an increase in the mineral content of the tissue. Using scanning electron microscopy (SEM), Isokawa, Kubota, and Kuwajima[19] showed that in areas of cervical abrasion, most dentinal tubules were completely filled with an inorganic substance but some remained with openings of various sizes. Mendis and Darling[20] used volume fraction analysis to show that peritubular dentin increased markedly with attrition. Again using SEM, Brannstrom and Garberoglio[21] had similar findings to those of Isowaka et al[19]. The concensus appears to be that there may still remain patent dentinal tubules in areas of cervical abrasion.

Proposed treatments for cervical tissue loss have varied almost as widely as suggested etiologies. Kornfeld[12] suggested occlusal adjustment to help stop the progress of the lesions. More recently, Xhonga, Wolcott, and Sognnaes[22] evaluated the use of gold, amalgam, or plastic dental materials as restorations. They noted that the rate of hard tissue loss was slowed but could still be detected on the surfaces

of these materials and on the adjacent tooth substance. In 1973, Xhonga and Sognnaes[23] tested the protective effects of various fluoride solutions on the progress of cervical lesions and concluded that a purely chemical treatment of the tooth surface is not adequate to control this progress. Harris, Phillips, and Swartz[24] in a laboratory and clinical study, evaluated the use of acid-etch resin materials without mechanical tooth preparation to restore cervical abrasion lesions. At the six month recall, nearly 50 percent of these restorations were lost as a result of a lack of bonding of the material to dentin.

While no study has dealt specifically with the incidence of sensitivity in cervical abrasion lesions, several authors have commented on this relationship. Bodecker[11] noted that patients with these lesions often complained of sensitivity to acids, cold, or sweets but that the intensity of the discomfort varied with time. Yet, in a case report of severe toothbrush abrasion, Arnim and Blackburn[16] stated that their patient never complained of tooth sensitivity. In another case report[17], even abrasion lesions severe enough to cause pulp exposures led only to occasional sensitivity. In their clinical study, Hollinger and Moore[7] reported that teeth with cervical abrasion had a relatively low incidence of sensitivity (4%), that being primarily to cold. Clinical experience suggests that while sensitivity of cervical abrasion lesions is not a common finding, neither is it a rare one. Therefore, it is valid to investigate this area of sensitive cervical anatomic deficiencies to develop better methods of treatment.

Mechanism of Dentinal Sensitivity

One difficulty encountered in treating cervical sensitivity is that the mechanism of stimuli transmission from dentin to the pulp is not fully understood. There are presently two theories concerning pain transmission through dentin: the transducer theory and the hydrodynamic theory.

The transducer theory states that odontoblasts and their processes act as a dentinal receptor mechanism and transmit sensory stimuli in a manner similar to nerve tissue conduction. This theory was given support by the work of Avery and Rapp[25] who reported finding significant concentrations of acetylcholinesterase within dentinal processes and in the region of the dentinoenamel junction. They suggested that the odontoblastic process acted as a neural receptor and synapsed with adjacent pulpal nerve endings. A later study by TenCate and Shelton[26], however, failed to corroborate these findings and using different laboratory techniques, Rapp and Avery were unable to duplicate their earlier results[27]. Indeed, several authors have reported that neither neural elements[28,29] nor odontoblastic processes[30,31] extend into mature dentin beyond a very short distance. In other studies, agents (including acetylcholine) which had caused pain when applied directly to pulp tissues failed to do so when applied to dentin[32,33]. Thus it is unlikely that an odontoblastic process functions like a nerve.

The second and more popular explanation for dentinal pain transmission is the hydrodynamic theory first proposed by Gysi in 1901[34]. This theory states that mechanical, chemical, thermal, or osmotic stimuli

cause a disturbance of the fluid contents of the dentinal tubule which is transmitted to mechanoreceptors in the pulp. Anderson and others[35-37] tested various solutions and suggested that with osmotic stimulation, fluid flow through dentin and pain production are related events. Brannstrom and Astrom[38] elicited pain when they applied dry absorbent paper to exposed dentin, but no pain was produced when the paper was soaked in isotonic potassium chloride. Brannstrom also investigated the relationship between increased air or water pressure and dentinal pain [39-41]. He concluded that applying a stream of air to exposed dentin caused evaporation of fluid from the tubule apertures which caused pain via flow of dentinal fluid. In a combined in vitro and in vivo study, Brannstrom, Johnson, and Linden[42] concluded that the pressure required to produce pain in cavities was of the same order as that required to produce a flow of fluid in the dentinal tubules. Reeder et al[43] described a method to measure the rate at which a fluid can filter through dentin. Beveridge and Brown[44] reported an increase in intrapulpal pressure when heat was applied to a tooth and a corresponding fall in pressure when cold was applied. Trowbridge et al[45] applied hot and cold stimuli to teeth and found that in all cases the patient's symptom response time was shorter than the time needed to produce a temperature change in the area of the pulpo-dentinal junction. They suggested that hydrodynamic forces may be capable of initiating generator potentials within sensory nerve endings. On an ultrastructural level, Roane et al[46] found a complex relationship between odontoblasts, their processes, and nerve structures in mature dentin.

Not all studies are in support of the hydrodynamic theory, however. Cavity preparations often result in aspiration of odontoblasts into dentinal tubules, a phenomenon which should cause a violent disturbance in the contents of these tubules. Yet, Kramer[47] found a lack of correlation between odontoblast aspiration and pain.

Thus, the mechanism of dentin sensitivity is not completely understood and indeed,all stimuli may not cause pain by the same mechanism. It would appear, however, that obturation of the dentinal tubules should reduce or eliminate sensitivity no matter what the mechanism.

Sensitivity Evaluation

The use of clearly defined methods of evaluating a patient's level of tooth sensitivity is important in determining the efficacy of various techniques or agents designed to reduce or eliminate that sensitivity. Many early studies[48-51] and even some recent ones[52-54] which proposed the use of a particular desensitizing agent had no explanation of the criteria used for evaluation of sensitivity. However, the general trend in the literature has been the development of techniques to quantify tooth sensitivity by applying controlled stimuli to teeth and eliciting the patient's response. This sensitivity evaluation has often been done in conjunction with an arbitrary rating scale whereby the patient is asked to judge the severity of the sensation both before and after the desensitizing agent or treatment is employed. Seltzer, Bender, and Ziontz[55] noted that the severity of pain felt by a patient is related to previous experiences and emotional state. This impression is supported by the clinical observation that the level of sensitivity for a patient

will vary with time. Nevertheless, in order to allow a scientific evaluation of various therapies designed to reduce tooth sensitivity, some system of sensitivity quantification based on applied stimuli is needed.

Fitzgerald[56] in 1956 was one of the first to publish a description of the use of stimuli applied to sensitive tooth areas before and after treatment. He used a cold air stream and scaling and recorded the patient's responses. Abel[57] used the same stimuli but had the patient rate the degree of effectiveness of the desensitizing agent.

Burman and Goldstein[58] evaluated tooth sensitivity by scratching cervical areas with a number 23 dental explorer. They also had their patients rate the benefit of a particular desensitizing agent as very good, good, questionable, or of no benefit. Bolden, Volpe, and King[59] used a similar technique and rating scale whereas several other studies simplified this rating scale to a "yes or no" sensitivity response by the patient upon explorer application[60-63]. Wei et al[64] observed their patient's eye responses during explorer probing as an indicator for sensitivity. Ayers and Agate[65] developed an apparatus to standardize the pressure of a mechanical stimulation of a tooth.

Several other authors tested desensitization agents by using only blasts of air applied to the sensitive area and having the patient rate the degree of sensation[66-69].

Hot and cold water application has also been used to test tooth sensitivity. In most of these studies, combinations of different stimuli were applied to the sensitive areas (including explorer scratching, hot/cold water, air blasts) and in many a rating scale was used[70-76].

Zelman and Hillyer[77] and Miller et al[78] used these stimuli plus a sugared oral rinse to evaluate tooth sensitivity.

In 1961, Naylor developed a thermoelectric tooth stimulator which could provide a precisely controlled hot or cold stimulus to a tooth[79]. This type of device was later used in clinical studies as a means of evaluating the efficacy of a particular desensitization therapy[80,81].

Smith[82] used a unique mechanical stimulating device to test for cervical sensitivity. The device could provide a calibrated lateral scratching force to the cervix of a tooth and could be accurately repositioned on the tooth being tested by means of a compound matrix. In his study, Smith used this mechanical stimulator as well as a thermoelectric tooth stimulator as already described. This combination of sensitivity evaluation techniques was subsequently used in several other studies[83-87].

Tarbet et al[88-90] used a digital display pulp tester to evaluate cervical sensitivity. The examiner would read from this display the voltage level being applied by the pulp tester at the time when the patient first perceived some sensation. They also used a one second blast of air from the dental unit air syringe and had the patient use a rating scale for this stimulus. They found that both testing methods were able to discriminate changes in sensitivity levels and there was a positive correlation between the two methods of evaluation. Stark et al[91] evaluated this pulp tester and found that the system gave reliable, accurate, and reproducible data.

Other techniques that have been suggested to evaluate pain or sensitivity include the use of a polygraph[92], use of verbal pain descriptors[93], and the use of a pain questionnaire[94].

In summary, a wide variety of techniques have been used to evaluate tooth sensitivity. The use of a simple, understandable patient response rating scale and controlled applied stimuli should give data with a maximum of scientific validity, reliability, and objectivity.

Treatment of Dentinal Hypersensitivity

Suggested therapies to reduce dentinal sensitivity have been many and varied and most have had either limited acceptance or questionable benefit.

Bodecker in 1933 recommended vaseline application to sensitive cervical areas[11] whereas other early remedies included the topical use of silver nitrate[95,96] or hot olive oil[97] or the ingestion of calcium tablets and vitamin-A rich foods[98]. Colaneri[99] suggested glycerine applied to sensitive cervical dentin as a cure whereas Jensen[100] recommended the topical use of a paste containing silver and zinc ferrocyanide and zinc chloride.

Fitzgerald[56] proposed the use of a dentifrice with 1.4% formalin as the active desensitizing ingredient. Others have also found this agent beneficial[51,57,58] but in a well-controlled double blind study, Smith and Ash[83] found the formalin containing dentifrice no more effective than the control.

In more recent times, fluoride in various forms has been used. These include sodium fluoride[48,49,88,91,101], stannous fluoride[78], sodium silicofluoride[50], and sodium monofluorophosphate[59,62,80]. Many authors suggested the use of iontophoresis to potentiate the effect of various fluoride formulations[66,69,72,102,103]. Again, there were dissenters who observed little benefit from some of these agents[81,87].

Other researchers have found a dentifrice containing strontium chloride to provide relief from cervical sensitivity[61,76,77,104,105] but again not all studies are in agreement with this finding[84]. Other agents that have been reported as effective include calcium hydroxide [73,86], potassium nitrate[53,89,90], and sodium citrate[63,64]. Greenhill and Pashley[106] tested over thirty topical desensitizing agents in vitro to evaluate their effects on the rate of fluid flow through dentin. Pashley et al[107] found that in dogs, the rates of fluid permeation in vivo and in vitro were very similar. Dayton, DeMarco, and Swedlow[85] found various "adhesive" restorative materials effective in treating sensitive root surfaces and Brannstrom, Johnson, and Nordenvall[54] recommended the use of a low viscosity resin to seal dentinal tubules and thereby block pain transmission. Low[108] reported that a glass ionomer cement effectively relieved sensitivity in cervical abrasion lesions in 90 percent of his patients.

It can be seen from the large numbers of suggested therapies to treat cervical sensitivity and the varied success of many of these,

that the ideal agent has yet to be found. Most agents are inconsistently effective or of benefit for only a short time and therefore new treatments are still being developed and tested.

Glass Ionomer Cements

A new formulation of a translucent cement described in 1972 by Wilson and Kent[109] as a glass ionomer cement appears to have combined several of the good qualities of the silicate and polycarboxylate cements. The formulation has been described by McLean and Wilson[110] as a reaction between an ion-leachable glass in a powder form and an aqueous solution of homo- and copolymers of acrylic acid. Crisp et al[111-113] describe the setting mechanism in detail. The material as initially developed combined an aluminosilicate glass with polyacrylic acid. Apparently the liquid rapidly decomposes the powder to form a siliceous hydrogel together with the polyacrylate salts of calcium and aluminum. In the early stages of the reaction only the calcium salt is formed and the material first sets to a gel-like consistency. Later the aluminum salts are formed and the cement fully sets. Wilson, Crisp, and Ferner[114] showed that the addition of certain acid chelating agents can improve the setting behavior of the system and increase the rate of hardening without decreasing the working time.

The favorable properties of the aluminosilicate polyacrylate (ASPA) material were summarized by McLean and Wilson[110] and they also reviewed the clinical applications[115]. The property perhaps of most interest to the clinician is the adhesion which takes place between

the material and tooth structure. This has been described as a true adhesion by intermolecular interactions of an ionic nature[116] as opposed to purely a mechanical-type retention as is seen with the composite acid-etch system. Hotz et al[117] investigated this adhesion phenomenon and described an effective bond between a glass ionomer material and enamel or dentin. When bond failures to enamel occurred, these were cohesive failures within the material and not at the interface between the material and the tooth. They also found a good bonding to dentin but this adhesion was weaker than the bond to enamel. Prodger and Symonds[118] also found good adhesion of an ASPA material to tooth structure, but Yedid and Chan[119] found only a minimal adhesion to dentin. Additionally, Hotz et al[117] found that a glass ionomer cement formed an effective adhesive bond to tin plated platinum or gold but not to pure platinum, gold, or to porcelain.

Another important property of a glass ionomer cement is its apparent ability to leach fluoride ions and therefore exert a cariostatic effect. Kidd[120] noted this effect using an artificial caries technique. Forsten[121] compared the fluoride release from a glass ionomer cement to a silicate cement and found more fluoride ion release from the glass ionomer cement even though it was less soluble. Wesenberg and Hals[122] examined the ionic uptake by enamel and dentin from a glass ionomer using microradiography and stated that the uptake of fluoride and aluminum ions in cavity walls should provide an anticariogenic property.

Kent, Lewis, and Wilson[123] compared a glass ionomer cement to existing dental cements such as silicate, polycarboxylate, zinc phosphate, a simple zinc oxide-eugenol (ZOE), and reinforced ZOE. They found that the compressive strength of the glass ionomer was greater than the zinc oxide-based cements because of the nature of the glass filler particles. The glass ionomer was somewhat stronger than the silicate and polycarboxylate and considerably stronger than zinc phosphate and ZOE in tensile strength. Also the initial acidity of the glass ionomer cement was less than cements based on phosphoric acid and it was slightly less soluble than silicate in weak acids.

McCabe, Jones, and Wilson[124] compared a glass ionomer cement to a composite material. The transverse strength of the ASPA material was considerably less than the composite and they recommended against the use of a glass ionomer in cavities where high stress would be applied. The translucency of the glass ionomer cement also compared poorly to the composite but the abrasion resistance of the ASPA material was considered adequate. McLean and Wilson[115] recommend against the use of a glass ionomer cement to restore large areas of labial enamel where esthetics is a factor because of the relative opacity of the material.

The pulpal response to any new dental material must be tested prior to widespread use and several investigators have examined the effects of the glass ionomer cements in vitro and in vivo. Dahl and Tronstad[125] compared the toxicity of a glass ionomer cement to a silicate cement in tissue culture and in monkey teeth. In vitro, a freshly prepared mix of the material was toxic but this decreased with time and was

non-toxic after a 24-hour setting time. In vivo, the material caused only mild pulp reactions. Tobias et al[126] confirmed the mild pulp response to a glass ionomer cement in human teeth and stated that the reaction was similar to that from a polycarboxylate cement. Pameijer, Segal, and Richardson[127] speculated that the milder pulp reaction to a glass ionomer cement as opposed to a phosphoric acid cement may be explained by the weaker acid makeup of the ASPA material and the larger molecular weight of the polyacrylic acid which might slow diffusion of irritants along the dentinal tubules.

The clinical application of the filling consistency of a glass ionomer cement with the most promise is probably the restoration of cervical abrasion lesions. This has been described in detail by McLean and Wilson[116]. The advantages are: 1) no cavity preparation is required in certain instances due to an adhesion of the material to tooth structure, 2) its cariostatic potential, and 3) its biological compatibility. Disadvantages are mainly the poor translucency (compared to a composite material) and the degradation by moisture if contaminated early in the setting reaction.

Charbeneau and Bozell[128] evaluated a glass ionomer cement to restore cervical erosion lesions and recorded data on material retention, color match, surface smoothness, margin discoloration and integrity, and caries at baseline and at one, three, and six month recall intervals. At six months, 95 percent of the restorations were still present, and in instances of margin discoloration this had not penetrated the tooth-restoration interface. There was no significant increase in roughness at six months. Flynn[129] compared Cervident to a glass

ionomer material to restore cervical abrasion lesions without prior preparation and after two years, 80 percent of the restorations of both materials were retained. Garcia et al[130] noted that restoring cervical defects with a glass ionomer cement contributed positively to gingival tissue health over a six-month period. Low[108] reported that a glass ionomer restoration was beneficial in sensitive cervical defects. Seluk and Smith[131] reported that patient acceptance was very high for a glass ionomer restoration primarily because extensive tooth preparation and anesthesia are not necessary.

In summary, the glass ionomer cements have certain favorable properties for restorative dentistry especially as used to restore cervical anatomic deficiencies. These include adhesion to tooth structure, possible cariostatic activity, and mild pulpal and gingival responses.

MATERIALS AND METHODS

Sixteen patients associated with The University of Michigan School of Dentistry consented to take part in this study. All 16 patients completed the required three appointments and constitute the final subject population. Thirty-two (32) teeth were treated for these 16 patients with no more than three teeth treated for any one patient. The patient population was composed of 11 males and five females. Their age ranged from 25 to 70 years with a mean age of 42 years. The breakdown of the 32 teeth treated is as follows:

maxillary molars	5
maxillary premolars	15
maxillary cuspids	2
maxillary incisors	4
mandibular molars	1
mandibular premolars	1
mandibular cuspids	1
mandibular incisors	3

Participation in this study required that the patient have a cervical abrasion lesion at least 1 mm. in depth which was sensitive either to toothbrushing, an air stream, or cold or warm water. The patients also had to be available for the three appointments over a time frame of approximately six to eight weeks.

One examiner performed all clinical procedures and recorded all experimental measurements. The procedures performed at each of the three appointments were identical for the sixteen patients. A health history was taken and an informed consent document was signed by each patient. This followed a detailed explanation of the intent, procedures, and potential consequences of the treatment.

First appointment: Initially, a pretreatment rating was given by the patient as to the overall sensitivity of the selected lesion, i.e.

0..... not sensitive
+..... slightly sensitive
++..... moderately sensitive
+++..... severely sensitive

The selected tooth was then pulp tested using a battery-powered digital pulp tester.* This pulp tester was applied to sound enamel adjacent to the abrasion lesion. The purpose of the pulp testing was to detect any possible pulpal changes during the course of the study.

Tactile sensitivity was next determined. The examiner brushed only the selected lesion with a moderate force for 10 seconds using a new soft-bristled toothbrush.** The patient then rated the sensitivity to this stimulus with the same rating scale, 0, +, ++, or +++.

Sensitivity to an air stream was then rated by the patient after application of a one second air blast from the dental unit air syringe held at a distance of 10 mm. from the moistened lesion. Adjacent

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*Analytic Technology Corp., Redmond, WA 98052
**Right Kind/Sub-G, Butler Co., Chicago, IL 60611

Figure 1. Sample pretreatment cervical abrasion lesion.

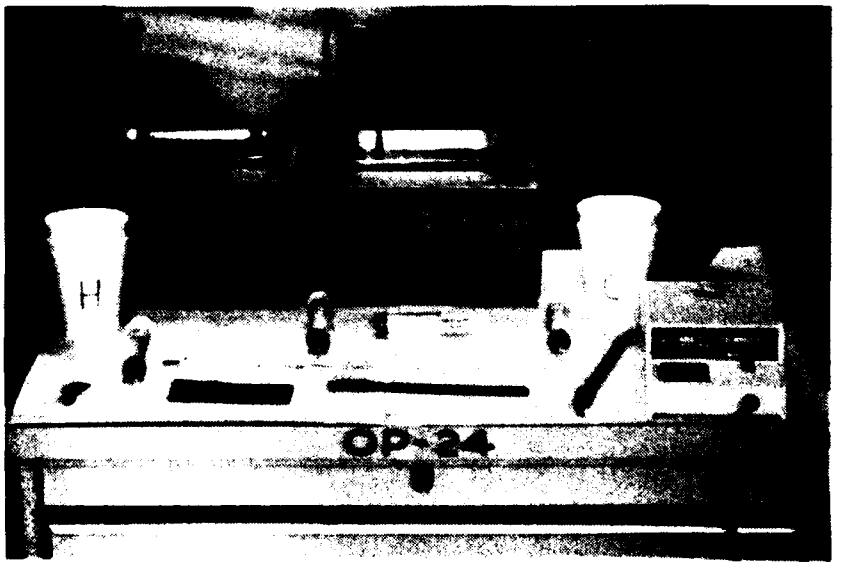

Figure 2. Experimental set-up.

teeth were covered by two layers of 28 gauge soft green wax* to limit the air stream to the selected lesion. Again, the patient responded after the stimulus using the same 0 to +++ sensitivity rating scale.

With the soft green wax remaining in position, the sensitivity of the lesion to cold and warm water applications was determined. The experimental set-up consisted of two water heating baths** and an ice water bath. The two water heating baths were set at 34°C. and 59°C. respectively. Two styrofoam cups were used to mix the appropriate temperature of cold or warm water. All water temperature determinations were made with the same Centigrage thermometer.*** A curved tip plastic irrigating syringe**** was used to direct the water at the lesion and a saliva ejector was used for gentle evacuation of the water.

Initially, the tooth was bathed intermittently for one minute with water at 34°C. to simulate the normal temperature of the vital pulp[45]. After evacuation of this water, the lesion was bathed with a volume of water at 29°C. ± 1°C. for three seconds. Immediately after this stimulus, the patient related to the examiner whether the tooth was sensitive to that temperature of water, ie. Yes or No. If Yes, then this was the baseline sensitivity level of the tooth for cold water application. If No, this water was evacuated and water at 34°C. was again used to intermittently bathe the tooth for one minute to prevent any cumulative cooling effect. At that point, another

*Kerr/Sybron, Romulus, MI 48174
**Teledyne Hanau, Buffalo, NY 14225
***Fisher Scientific, Cat. #14-985-B, range -20°C. to 110°C.
****Monoject, St. Louis, MO 63103

Figure 3. Application of the tactile stimulus to the abrasion lesion.

Figure 4. Application of the air stream stimulus to the abrasion lesion.

volume of water at 24°C. ± 1°C. was directed at the lesion for three seconds and again a Yes or No determination for sensitivity was given by the patient. This alternating of 34°C. water applied for one minute and a three second application of an increasingly colder temperature of water applied in increments of 5°C. ± 1°C. continued until a temperature of cold water was reached at which the patient first reported tooth sensitivity. This baseline level was recorded. The limit for temperature testing, if reached, was 4°C. for cold water as this temperature approximates that of an iced beverage.

Prior to warm water sensitivity testing, the tooth was bathed intermittently with 34°C. water for two minutes to eliminate any cooling effects from the cold water applications. Then, increasingly warmer water in increments of 5°C. ± 1°C. directed at the lesion for three seconds was alternated with 34°C. water applied for one minute until a temperature of warm water was reached at which the patient first reported tooth sensitivity. The limit for temperature testing, if reached, was 59°C. for warm water as this temperature approximates that of a heated beverage.

Four separate irrigating syrings were used. One was used only to direct the test water at the lesion and another was used only to direct 34°C. water at the lesion. The two other syringes were used to carry cold or hot water to the respective mixing cup to prepare each temperature increment of test water. The syringe used for the test temperature of water was flushed with 34°C. water between the cold and warm water applications.

After the sensitivity testing was completed, the green wax was removed and the lesions were restored with a glass ionomer cement* according to the manufacturer's recommendations. First, the tooth was cleaned with a flour of pumice and water slurry using a soft rubber cup rotating in a slow-speed handpiece. Then the appropriate shade of restorative material was selected. Isolation of the tooth was accomplished with cotton rolls and Dri-Angles** and a saliva ejector was used for evacuation. The lesion was thoroughly dried with cotton pellets and a gentle air stream.

The selected shade of powder was measured and dispensed on the supplied mixing pad as was a single drop of the liquid provided. The material was mixed with a plastic spatula provided by the manufacturer to a proper consistency in approximately 30 seconds and still retained its surface gloss when it was carried to the tooth. The surface gloss indicates that the material still retains its adhesive character. The material was flowed into the lesion with a metal applicator provided and developed to a slight overcontour. Care was taken to avoid air entrapment during the mixing and placing of the material. The filling was then covered with a varnish provided by the manufacturer and this was dried with a gentle air stream as recommended. The purpose of the varnish is to protect the restoration from moisture contamination during the early stages of its setting.

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*Fuji Ionomer Type II, G-C International Corp., Scottsdale, AZ 85258
**Theta Corp., Niagara Falls, NY 14302

The restoration was left undisturbed for five minutes at which point the patient was dismissed with instructions not to disturb the area of the restoration for a period of 24 hours.

No patient required anesthesia for the placement of the restorations and no pulpal medicament was used under any of the restorations.

Second appointment: The patient returned approximately one week later and prior to any instrumentation, gave a rating as to the overall sensitivity of the restored lesion since the first appointment. For this, the same 0 to +++ sensitivity rating scale was used.

The restoration was then finished and polished. First, excess material was reduced using a very fine flame-shaped diamond stone* operated in a high-speed handpiece with water spray. A 7901, 12 blade carbide finishing bur** was then used in a high-speed handpiece with water spray to establish proper contour and marginal extent. Polishing was accomplished using rubber-backed slow-speed polishing discs.***

After polishing the fillings, the teeth were pulp tested and then sensitivity determinations were made for tactile, air stream, and cold/warm water stimuli. This was done in an identical manner as that described for the initial appointment.

Third appointment: The patient returned approximately six to eight weeks after the initial appointment. During this visit there was no instrumentation of the teeth other than that required for the sensitivity determinations. The patient first gave an overall sensitivity rating

*Smooth-Cut V16ff, G-C International Corp., Scottsdale, Az 85258
**Midwest American, Des Plaines, IL 60018
***Sof-Lex Discs, 3M Co., Dental Products, St. Paul, MN 55101

Figure 5. Application of water to the abrasion lesion.

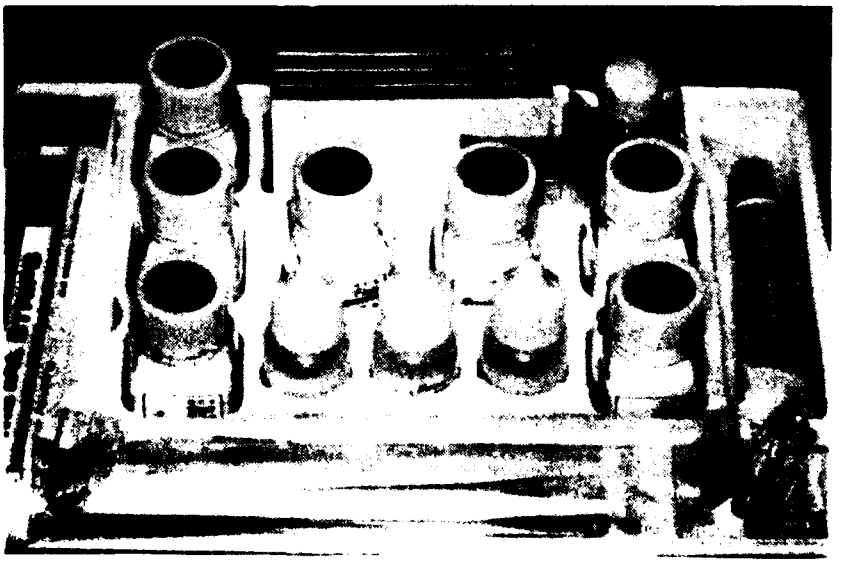

Figure 6. Glass Ionomer restorative material.

since the restoration of the tooth using the 0 to +++ rating scale. Then the tooth was pulp tested as already described. Again, sensitivity of the restored lesion was determined to tactile, air stream, and cold/warm water stimuli as previously described.

Statistical analysis: For purposes of statistical analysis, the case population of 32 teeth was grouped together and the results compiled.

For the overall rating, the tactile rating, and the air stream rating (ordinal scale), the data is reported as the percentage of cases that show improvement, ie. reduced sensitivity, for each time interval. The 95 percent confidence interval will be reported over each time interval. In addition, the number of reversals seen in each time period is reported. A reversal is defined as a rating which indicates an increase in sensitivity as compared to an earlier rating.

For the cold/warm water testing (interval scale), the average sensitivity level and range of responses (in °C.) is reported for each time interval. Any negative response at a temperature extreme (indicating "not sensitive" at 4°C. or 59°C.) was treated as if it was a positive response at that extreme. Again, the percentage of cases that show improvement over each time interval is reported as is the 95 percent confidence interval for this data and the number of reversals.

Figure 7. Restored cervical abrasion lesion.

RESULTS

All sixteen patients completed the required three visits. The average time intervals and range in number of days between the three appointments (T1, T2, T3) for the 32 cases appears in Table 1.

Table 1

Time Between Three Appointments
(32 cases)

Time Period	Average Number of Days	Range in Days
T1 to T2	7.1	5-14
T2 to T3	49.5	38-66
T1 to T3	56.6	46-73

The manufacturer's suggested normal response ranges for the pulp tester used in this study are as follows:

incisors..... 10 to 40
premolars..... 20 to 50
molars..... 30 to 70

All but one of the treated teeth yielded a positive response, indicating pulp vitality, at each appointment. Nine of the teeth (28.1 percent) yielded a response below the normal response range at one or more appointments. No teeth responded above the normal response range (see appendix). One case (Pt. H, tooth #11) yielded no response to pulp testing at any of the three visits.

Table 2 shows the compiled Overall Sensitivity Ratings for the 32 cases. It can be seen that 19 teeth were rated as moderately or severely sensitive at the initial visit (T1) yet only one tooth was rated as moderate or severe at T2/T3. There were seven reversals (indicating increased sensitivity) from T2 to T3 but no reversals in the other time periods. As seen in Table 2, 90.6 percent of the teeth improved from T1 to T3.

Table 3 shows the compiled Tactile Sensitivity Ratings for the 32 cases. Sensitivity to toothbrushing was not as commonly seen as that to other stimuli as only 19 teeth (59.4 percent) were initially rated as having any degree of sensitivity to this tactile stimulus. The percent improvement of the 32 cases was 43.8 from T1 to T3. When only the 19 teeth initially rated as sensitive to toothbrushing were analyzed, 14 of them (73.7 percent) showed a reduced sensitivity from T1 to T3. For these same 19 teeth, there were three reversals from T2 to T3. No reversals were observed in the other time periods. There was one reversal (Pt. M, tooth #5) from T1 to T2 in the group of 13 teeth that were initially rated as not sensitive to toothbrushing.

Table 4 shows the compiled Air-Stream Sensitivity Ratings for the 32 cases. It can be seen that 30 teeth were rated as having some degree of sensitivity to this stimulus at T1 with 20 teeth rated as sensitive at T2 and only 12 teeth rated as having any sensitivity at T3. Of the 32 cases, 78.1 percent showed a decrease in sensitivity from T1 to T3. There were four reversals recorded from T2 to T3 and three

reversals recorded from T1 to T3. One patient (Pt. N) accounted for most of the reversals to the Air-Stream stimulus (see appendix).

Table 5 shows the compiled Cold Water Sensitivity Levels for the 32 cases. As can be seen, 87.5 percent of the teeth showed improvement from T1 to T3 with the average temperature of cold water sensitivity being decreased by 10.9°C. over this time period. There were two reversals from T1 to T2, four reversals from T2 to T3, and one reversal from T1 to T3.

Table 6 shows the compiled Warm Water Sensitivity Levels for the 32 cases. As shown, 68.8 percent of the teeth showed improvement in warm water sensitivity from T1 to T3. The average improvement in this time interval was 7.7°C. There were two reversals recorded from T1 to T2, five reversals from T2 to T3, and one reversal recorded from T1 to T3.

Table 2

Overall Sensitivity Rating (No stimulus)
(32 cases)

Rating	T1	T2	T3
0	0	25	24
+	13	6	7
++	15	1	1
+++	4	0	0

Percent Improvement

T1 to T2 = 93.8 (83-97)*

T2 to T3 = 15.6 (7-27)*

T1 to T3 = 90.6 (79-96)*

*95% Confidence Interval

Key:

0..... not sensitive
+..... slightly sensitive
++..... moderately sensitive
+++..... severely sensitive

Table 3

Tactile Sensitivity Rating
(32 cases)

Rating	T1	T2	T3
0	13	24	24
+	12	8	7
++	7	0	1
+++	0	0	0

Percent Improvement

T1 to T2 = 46.9 (34-59)*

T2 to T3 = 6.3 (2-16)*

T1 to T3 = 43.8 (32-56)*

*95% Confidence Interval

Key:

0..... not sensitive
+..... slightly sensitive
++..... moderately sensitive
+++..... severely sensitive

Table 4

Air Stream Sensitivity Rating
(32 cases)

Rating	T1	T2	T3
0	2	12	20
+	13	17	6
++	8	3	6
+++	9	0	0

Percent Improvement

T1 to T2 = 62.5 (48-75)*

T2 to T3 = 28.1 (17-42)*

T1 to T3 = 78.1 (66-88)*

*95% Confidence Interval

Key:

0.....not sensitive
+.....slightly sensitive
++.....moderately sensitive
+++.....severely sensitive

Table 5

Cold Water Sensitivity Level
(32 cases)

(test range: 29°C. to 4°C.)

	T1	T2	T3	Percent Improvement
average sensitivity level (°C.)	22.6	16.0	11.7	T1 to T2 = 78.1 (66-88)*
				T2 to T3 = 59.4 (47-73)*
				T1 to T3 = 87.5 (77-94)*
range (°C.)	14-29	4-29	4-24	*95% Confidence Interval

Table 6

Warm Water Sensitivity Level
(32 cases)

(test range: 39°C. to 59°C.)

	T1	T2	T3	Percent Improvement
average sensitivity level (°C.)	46.0	51.8	53.7	T1 to T2 = 68.8 (55-80)* T2 to T3 = 31.3 (19-43)* T1 to T3 = 68.8 (55-80)*
range (°C.)	39-59	39-59	39-59	*95% Confidence Interval

DISCUSSION

While the incidence of sensitivity in abrasion lesions of a large population is unknown, it was observed from the sample in this study that sensitive abrasion lesions occurred more frequently in maxillary teeth with a majority of these seen in the premolar area. Perhaps these areas were more sensitive to the patient because they were less protected by soft tissues and saliva, and therefore more exposed to changes in the environment. Indeed, this exposure and visibility may also make abrasion lesions of maxillary teeth a more important esthetic concern to a patient.

In this study, the experimental design permitted comparison of certain characteristics before and after treatment. Thus each tooth served as its own control. In order to get as large a population as possible, all eligible cases were treated using the same therapy and treatment was not withheld in any instances. A future study might attempt to compare two sensitive abrasion lesions in the same mouth, one treated with a glass ionomer cement restoration and another with a desensitizing dentifrice.

In the present study only lesions of 1 mm. or greater in depth were selected for treatment. This decision was made in the belief that a minimal depth would provide an adequate bulk of restorative material and therefore not require any preparation of hard tooth tissue to enhance retention. With the selection of at least 1 mm. deep, caries-free lesions, it was not necessary to alter the tooth surface by rotary instrumentation. Such tissue removal might have changed the responsivity of the tooth at subsequent appointments.

Pulp testing was performed in this study to detect any possible pulpal response that might result from the testing methods or the restorative material. One must recognize that in the normal clinical situation, several other diagnostic tests are used in conjunction with this pulp testing in an attempt to determine the state of health of the dental pulp. The pulp tester gives a relative value which should be compared to readings of adjacent and contralateral teeth and evaluated in the context of other diagnostic data. The defining of a "normal range" of responses to the pulp tester used in this study is only of importance when used as part of a complete diagnostic procedure. The response of several teeth at a level below this "normal range" is therefore not considered significant, and it is concluded that the pulp tester revealed no significant pulpal changes attributable to the testing methods or restorative material used in this study. The finding that one tooth (Pt. H, tooth #11) had no response to the pulp tester at any of the three appointments cannot be explained at this time. It should be noted, however, that this particular case did show a variable benefit

from the therapy and one might question whether the pulp of this tooth was indeed in a normal state of health at the outset. Such a determination could only be made at this time by a histologic evaluation.

The use of a sensitivity rating scale by the patient, even with its shortcomings, is considered a desirable way of evaluating such a subjective phenomenon and does provide useful information. It is understood that this decision by the patient can be affected by subjective variables such as moods, emotions, previous experiences, or even the desire to please (or displease) the examiner. Indeed, observation of patient responses to the stimuli often revealed hesitation in decision-making on the part of the patient. Often the patient related that one or even two of the possible response options could be eliminated, but occasionally there was not a clear-cut choice as to the appropriate response. One must take this understanding into consideration when evaluating results obtained from such a rating scale.

The number of possible options or response levels of a rating scale is also an important variable. This kind of study requires a rating scale that is easy for both the practitioner and the patient to use and understand, with enough possible response levels to reveal a difference when one exists. However, there should not be too many response options that would require difficult discriminations and produce data devoid of clinical meaning. It was believed that the patient response rating scale used in this study fulfilled the desired requirements. Using this rating scale, 90.6 percent of the treated teeth showed improvement in overall sensitivity from the beginning of

the study to the end. None of the teeth described by the patient as "severely sensitive" initially were so judged at either the T2 or T3 recalls. Only one (1) of 15 teeth initially described as "moderately sensitive" were so described at T2 and T3.

As observed in these results, toothbrushing was not a great problem as a noxious stimulus to most patients. Brushing was selected as the tactile stimulus in this study because it could deliver a generalized stimulus to the cervical area of a tooth. In contrast, an explorer scratch, while being able to deliver a localized stimulus to a small area, could obviously not be reapplied to this same area after a restoration was placed. Additionally, toothbrushing represents a tactile stimulus more commonly experienced in the mouth.

A problem is recognized here in that while it was relatively easy to prevent contact of the toothbrush with adjacent teeth, it was difficult to prevent contact with the gingival tissues immediately adjacent to the abrasion lesions. Indeed, a few patients commented that they had some difficulty differentiating between tooth sensitivity and soft tissue sensation. In one case (Pt. M, tooth #5) the patient reported at the second appointment that the slight sensitivity experienced might have been related more to "frictional heat" produced by 10 seconds of toothbrushing than to the actual tactile sensation of the toothbrush against the restored cervical area of the tooth. Still, it is believed that the use of toothbrushing as a tactile stimulus in this study was appropriate and that it can be used to adequately distinguish changes in tactile sensitivity before and after the

restorations are placed. Using this tactile stimulus, 73.7 percent of the teeth that initially had any degree of sensitivity showed improvement at the end of the study.

The most common complaint of patients with regard to sensitive abrasion lesions is a sensitivity to cold. Therefore, the results seen with the air-stream and cold water stimuli take on added importance and clinical significance. The air-stream stimulus to a moistened lesion created both a cooling and a dehydrating effect. This simulated the contact of inspired air on a normally wet tooth surface. The use of the wax covering on the adjacent teeth provided an effective barrier to limit the air-stream to the test lesion. With the air-stream stimulus, 78.1 percent of the treated teeth showed decreased sensitivity from the beginning of the study to the end.

With the cold/warm water stimuli, a Yes" or "No" rating by the patient to a changing but specific temperature of water was thought to be a more reliable indicator of tooth sensitivity than a choice of a response rating to one test temperature of water. It was believed that such a response by a patient would be less susceptible to subjective influences than choosing from among several different response levels.

The three second application time of the specific temperature of test water was selected to prevent any temperature change in the tooth at the level of the pulpodentinal junction. Cervical sensitivity may be considered to be a stimulus/response phenomenon initiated at the surface of the tooth rather than at deeper levels. Therefore, a three

second stimulus application would allow a superficial sensory response yet minimize any pulpal response originating at the pulpodentinal junction. This deeper response might occur with a longer water application time. In actual patient experience, however, cold or warm foods and beverages may be in contact with teeth for a longer time period.

The bathing of the test tooth with 34°C. water before each successive application of test water was performed to return the dental pulp to its normal (original) level. If this attempt were not made, the later water applications may have initiated a pulpal response at a different level of sensibility. However, it cannot be stated with certainty at this time whether a one minute application of water approximating the temperature of the normal pulp would indeed return the tooth to its normal responsivity.

As with the tactile stimulus, the water applications contacted the gingival tissues immediately adjacent to the abrasion lesions. This may have caused a problem in differentiating between tooth sensitivity and soft tissue sensation, especially at the extreme of warm water testing.

It is believed, however, that the cold/warm water testing method described is easy to perform, reproducible, and a relatively objective method of determining the degree of sensitivity of a tooth. As shown, there was a significant improvement to cold sensitivity as 87.5 percent of the cases showed decreased sensitivity after restoration placement. The improvement seen for a warm water stimulus was less

striking, but still substantial as 68.8 percent of the cases showed decreased sensitivity to warm water application.

The 95 percent Confidence Interval means that, based on our sample population, we are 95 percent sure that the true proportion of improvement for the total population will be within this interval.

It is interesting to look at the number and distribution of reversals, a rating indicating an increase in sensitivity as compared to an earlier rating. The distribution of reversals is as follows:

T1 to T2 = 5
T2 to T3 = 23
T1 to T3 = 5

It can be seen that most reversals, nearly 70 percent, occurred from T2 to T3, a time interval averaging 49.5 days. In comparison, there were only five reversals from T1 to T2, a time interval averaging 7.1 days. It is believed that this difference is due to the different time interval in that a certain level of improvement in a shorter time period may be more apparent and striking to a patient, thereby leading to an improved rating, than the same level of improvement might appear over a much longer time period. A reversal or a lack of improvement seen at T2 might be related to the instrumentation required for finishing and polishing the restoration, which occurred at that appointment prior to any sensitivity testing.

Of all the possible reversals from T1 to T3 from the 32 cases (160 total possible) there were only five (3.1 percent). This indicates the lack of irritation associated with the treatment regimen and therefore

there exists a low potential for this therapy to exacerbate the patient's problem.

The relatively simple handling of the statistical data in this study was based partly on the sample size treated. It was believed that no additional information of any import could be gained by a more complex breakdown of the data with the relatively small sample size. Additionally, in reporting the results as a percent improved, this can enable a practitioner who might consider using this treatment to evaluate and estimate the potential benefit to his/her patient.

For statistical calculations, a "No Response" by a patient at an extreme of cold or warm water was treated as a "Yes" response at that level. This would cause the results to show the material as being less effective than in actuality. In fact, there were 26 instances in the 32 treated teeth where the patient felt no sensitivity at an extreme of cold or warm water.

As for the glass ionomer cement itself, the material handled quite well, it was easy to mix and apply to the tooth, and gave a well-finished restoration with good margins. No restorations were lost due to failure of the adhesive bond during the course of the study.

Some difficulty was encountered in trying to use a matrix to shape and condense the material. Cervical abrasion lesions, as opposed to a preparation for Class 5 caries, tend to have rather indistinct proximal margins which often extend into the proximal embrasures. Additionally, the gingival extent of an abrasion lesion is often indistinct. This lack of distinct cavosurface angle made it

difficult to routinely adapt any available cervical matrix to completely cover the abrasion lesions and still provide for a good contour in the restoration. Therefore, an add-on technique without the use of a matrix was required. Also, the key time period for the glass ionomer material to develop adhesion to the tooth is the first few minutes after being applied. Thus, the technique used provided for a minimum of handling and disruption of the material during this critical time period.

As stated earlier, the cervical extent of an abrasion lesion is often indistinct, tending to gradually blend with the normal contour of the tooth at or below the level of the soft tissues. Additionally, it is assumed that cervical sensitivity is primarily a phenomenon of supragingival tooth structure. Therefore, when the gingival extent of an abrasion lesion was not obvious, the restoration was extended to and finished at the gingival tissue margin. No subgingival restorations were placed. One patient (Pt. J, tooth #14), however, had an abrasion lesion which had a distinct, supragingival cervical margin. This restoration was placed within the extent of the abrasion lesion so as not to alter the normal contour of the unaffected tooth structure. Consequently, there remained some exposed dentin between the cervical extent of the restoration and the free gingival margin due to a small degree of gingival recession. As can be seen in the raw data (see appendix), this patient received little benefit in the form of reduced sensitivity from the treatment.

The esthetic results of the restorations as observed by most patients were pleasing. Usually the shade matching was good but there was some increased opacity as compared to a composite restoration. In cases of a shade mismatch the restoration usually appeared too light.

It can be concluded that as a restorative material for sensitive cervical abrasion lesions, a glass ionomer cement provided significant reduction in sensitivity to tactile, air-stream, and cold and warm water stimuli. Future studies may be able to use the methodology in the present study to compare a glass ionomer cement to a desensitizing dentifrice using a controlled, split-mouth experimental design. An additional study might also use a large patient population in a cross-sectional design to investigate the incidence of sensitivity in cervical abrasion lesions. This would show the frequency of this problem and might lead the dental profession to seek improved therapies.

SUMMARY

Sixteen adult patients with sensitive cervical abrasion lesions consented to take part in a study aimed at evaluating the effect upon the sensitivity of a glass ionomer cement to restore these lesions. Thirty-two lesions were treated for these patients with no more than three treated for any one patient. The sensitivity of the abrasion lesions was determined by application of controlled tactile, air-stream, and cold and warm water stimuli to the areas both before and after the restorations were placed. In addition, the patients subjectively rated the overall sensitivity of the teeth without any applied stimulus.

Three appointments were required. At the first visit following pulp testing of the teeth, sensitivity determinations to the various stimuli were made. Then the abrasion lesions were restored with a glass ionomer cement following the manufacturer's recommendations. No preparation of tooth tissue was used to enhance retention. At the second appointment approximately one week later, the restorations were finished, and pulp testing and sensitivity determinations were repeated. At the third visit six to eight weeks later, pulp testing and sensitivity determinations were again accomplished.

The data for the 32 teeth was compiled and reported as the percent of cases improved for each applied stimulus. Results revealed a significant improvement to all the stimuli over the course of the study. There was no evidence of any pulpal changes of the teeth caused by the test methods or restorative material used in this study.

The glass ionomer cement had good clinical handling characteristics and provided a well-contoured, marginally sound, esthetic restoration.

Cont'd

CONCLUSIONS

Based on the findings of this study the following conclusions are made.

1. A glass ionomer cement used to restore sensitive cervical abrasion lesions provides a clinically significant reduction in sensitivity to tactile, air-stream, and cold and warm water stimuli.
2. Thermal stimuli in the form of an air-stream or cold water produces the greatest patient response.
3. Tactile stimuli in the form of toothbrushing elicited a less severe patient response than did the thermal stimuli.
4. A glass ionomer cement restoration is useful to treat hypersensitive cervical anatomic deficiencies.

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APPENDIX

APPENDIX I

HUMAN SUBJECTS REVIEW APPLICATION

TO: INVESTIGATORS APPLYING TO THE USPHS FOR SUPPORT OF CLINICAL RESEARCH AND INVESTIGATION INVOLVING HUMAN BEINGS.

FROM: THE UNIVERSITY OF MICHIGAN, SCHOOL OF DENTISTRY COMMITTEE ON CLINICAL RESEARCH AND INVESTIGATION INVOLVING HUMAN BEINGS.

In fulfillment of Public Health Service and University policies, this Committee must, in respect to your research project and/or grant application, independently review: 1) The rights and welfare of the individual or individuals involved; 2) The appropriateness of the methods used to secure informed consent; and 3) The risks and potential medical benefits of the investigation. In order for the Committee to do this, please provide the following information.

1. Project Title and grant number:

   Evaluation of a Glass Ionomer Restoration to Treat Hypersensitive Cervical Anatomic Deficiencies.

2. Inclusive dates of project: 1 May 1982 - 30 April 1983

3. In what ways will the human beings be involved in your investigation? Please be specific.
   Consenting adults with sensitive cervical erosion or abrasion lesions will have these lesions restored with a glass ionomer cement restoration. Prior to and after restoration, the sensitivity of these lesions to normal toothbrushing, a stream of air, and cold and warm water will be graded.

4. a) Are there risks of any kind to human participants beyond those usually involved in dental clinical practice. If yes, please explain in detail:
   No risks beyond those usually involved in dental clinical practice.

   b) Briefly state the potential benefits of this research:
   Potential benefits derived from this study will include a greater knowledge of the usefulness of a glass ionomer cement to treat sensitivity in a cervical anatomic deficiency with a restoration that requires no mechanical tooth preparation. The use of a restoration in this situation as opposed to a topical desensitizing agent may help prevent further abrasion and weakening of the tooth. The use of specific calibrated stimuli in this study to test sensitivity allows for an objective grading by the patient of the degree of sensation perceived.

5. a) Outline the procedure by which the subject is to be fully informed of the nature of this research, the potential hazards and the potential benefits prior to giving his consent to participate:
   The potential patient selected for this study will be presented the enclosed consent form and a discussion of the study will be presented with the opportunity for the patient to ask and have answered related questions.

   b) How will consent be obtained?
   On a signed, written form.

   c) If written, please include form. Copy enclosed.

6. a) What measures will be employed to protect human participants (subjects) from the risks stated?
   All of the measures usually employed with regard to restorative treatment procedures.

b) What measures will be used to protect the rights and welfare of human subjects? Should any unexpected change occur to the dentition the study will be discontinued. The patient's eligibility for treatment within this school will not be altered by his decision to enter into or subsequently withdraw from this study. The patient may deny entry or withdraw participation from the study without recourse.

c) Please include protocol explanation on separate sheet. Include:

1. Project Plan
2. Methodology
3. Significance

Copy enclosed.

Gerald T. Charbeneau, D.D.S., M.S.	Sgd.
NAME OF DEPARTMENT HEAD	SIGNATURE
Edward B. Mandel, D.D.S.	Sgd.
NAME OF INVESTIGATOR	SIGNATURE
Resident, Graduate Operative	
TITLE AND DEPARTMENT	DATE

April 28, 1982

Date

MEMO TO: Gerald T. Charbeneau, Chairman, Operative Dentistry

FROM: James K. Avery, Chairman, School of Dentistry Review Committee

SUBJECT: Clinical Research and Investigation Involving Human Subjects

REFERENCE: EVALUATION OF A GLASS IONOMER RESTORATION TO TREAT HYPERSENSITIVE CERVICAL ANATOMIC DEFICIENCIES

Principal Investigator: Edward B. Mandel, D.D.S.

Upon review of the research plan submitted on behalf of the principal investigator, the School of Dentistry Committee on Review Grants for Clinical Research and Investigation Involving Human Subjects has determined independently that the rights and welfare of the individuals involved in this research are carefully guarded. The methods used to obtain informed consent are appropriate. The risks to the individuals involved are felt to be minor, and the potential health benefits of this investigation are of importance.

A copy of this memorandum is being routed to the principal investigator. This memorandum in addition to indicating favorable review, will emphasize the principal investigator's obligation to advise the Committee of any change in the protocol which might bring into question the involvement of human subjects in a manner at variance with the considerations on which the prior approval was based.

Sgd.

Signature

APPENDIX III

INFORMED CONSENT DOCUMENT

The University of Michigan

SCHOOL OF DENTISTRY ANN ARBOR, MICHIGAN 48109

CONSENT FORM

Name of Project: Evaluation of a Glass Ionomer Restoration to Treat Hypersensitive Cervical Anatomic Deficiencies

As part of a continuing research program in the Department of Operative Dentistry to define better restorative materials and procedures, we are investigating the use of a glass ionomer cement (a tooth-colored filling) on sensitivity in a cervical abrasion lesion (a notch at the gum-line of a tooth). This study will evaluate the sensitivity of these notches before and after the fillings are placed.

Participation in this study requires that you have such an abrasion lesion which is sensitive either to touch, air, or cold or warm water. During the study, three visits will be needed, the second approximately one week after the first and the third visit approximately eight weeks later. The sensitivity will be rated during the application of normal toothbrushing, a stream of air, and cold and warm water. Due to the nature of a study dealing with sensitivity, some slight discomfort of a short duration may be expected. At the first visit, the tooth will be tested for sensitivity and then restored using standard, accepted techniques. While no drilling of the tooth is required, you may have local anesthesia during the placement of the filling if this appears necessary. At the second visit the filling will be polished and at this and the next visit the sensitivity will again be rated. The last (third) appointment is required as an additional appointment for study purposes only.

- -

I agree to participate in this research study. This study has been explained to me and I understand its purpose and the procedures involved. I have had the opportunity to discuss this project with Dr. Edward Mandel and my questions have been satisfactorily answered.

During this study, I consent to the taking of photographs to be used solely for teaching purposes as educational material, and for publication in scientific journals.

I understand that I am free to withdraw my consent and to discontinue participation in this project at any time without jeopardizing my eligibility for treatment at this institution.

I understand that the University of Michigan will provide first-aid medical treatment in the unlikely event of physical injury resulting from research procedures. Additional medical treatment will be provided in accordance with the University's determination of its responsibility to do so. The University does not, however, provide compensation to a person who is injured while participating as a subject in research.

_____ _____

Patient's signature Date

_____ _____

Witness Date

APPENDIX IV

SAMPLE DATA SHEET

Patient # _____ Case # _____

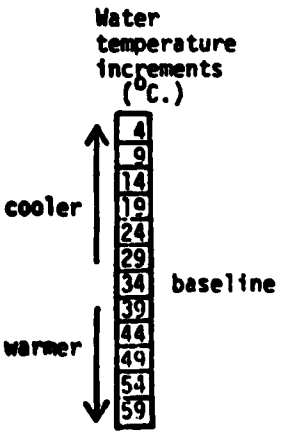
Patient Name _____ Reg. # _____ Age _____

Address _____ Phone # _____ Consent signed _____

	Date	Tooth	Pulp test	Overall rating	Tactile	Air Stream	Water tests Cold	Water tests Warm
Initial visit								
Second visit								
Third visit								

Sensitivity rating scale:

0 ..... not sensitive
+ ..... slightly sensitive
++ ..... moderately sensitive
+++ ..... severely sensitive



APPENDIX V

Constituents of Fuji Type II glass ionomer cement (as described by the manufacturer):

Powder - an alumino-silicate glass powder containing silicon, aluminum, calcium, sodium, phosphorus, fluorine, and oxygen

Liquid - a polycarboxylic acid solution containing acrylic, itaconic, and tartonic acids

Batch numbers:

Powder - Shade 21..... 231011
Shade 22..... 221011
Shade 23..... 221011
Shade 24..... 271011
Shade 28..... 271011

Liquid - Batch no. 261011

APPENDIX VI

DATA SHEET KEY

T1, T2, T3 = appointment 1,2,3

P.T. = pulp test reading

O.R. = Overall rating of sensitivity (no stimulus)

T.R. = Tactile rating for sensitivity

A.S.R. = Air stream rating for sensitivity

Cold - Temperature of cold water sensitivity (°C.)

Warm - Temperature of warm water sensitivity (°C.)

N.R. = no response (at 4°C. for Cold or 59°C. for Warm)

Rating scale:

0 ..... not sensitive
+..... slightly sensitive
++..... moderately sensitive
+++..... severely sensitive

DATA

-Patient A, male, age 59

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
Tooth #5							
T1	7 Jun 82	41	++	0	0	24	44
T2	14 Jun 82	36	0	0	0	N.R.	59
T3	27 Jul 82	41	0	0	0	4	59
Tooth #12:							
T1	7 Jun 82	45	++	0	++	19	44
T2	14 Jun 82	14	0	0	0	24	44
T3	27 Jul 82	18	0	0	0	19	49

-Patient B, male, age 27

Tooth #3:							
T1	15 Sep 82	33	+	0	+++	24	49
T2	22 Sep 82	47	0	0	0	14	59
T3	10 Nov 82	40	0	0	0	14	N.R.
Tooth #14:							
T1	15 Sep 82	35	+	0	+++	24	49
T2	22 Sep 82	37	0	0	0	14	59
T3	10 Nov 82	40	0	0	0	14	N.R.

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient C, male, age 29							
Tooth #12:							
T1	20 Sep 82	36	+++	+	++	19	59
T2	27 Sep 82	44	0	0	+	14	N.R.
T3	17 Nov 82	30	0	0	+	4	N.R.
Tooth #13:							
T1	20 Sep 82	35	++	0	++	24	54
T2	27 Sep 82	42	+	0	++	19	49
T3	17 Nov 82	22	0	0	+	14	N.R.
-Patient D, female, age 29							
Tooth #5							
T1	24 Sep 82	34	+	+	++	14	44
T2	8 Oct 82	36	0	0	0	4	N.R.
T3	24 Nov 82	31	0	0	0	N.R.	N.R.
-Patient E, male, age 33							
Tooth #14							
T1	29 Sep 82	42	+	0	+	24	N.R.
T2	6 Oct 82	32	0	0	0	14	N.R.
T3	24 Nov 82	43	0	0	0	9	N.R.

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient E							
Tooth #19:							
T1	29 Sep 82	46	+	0	+++	19	54
T2	6 Oct 82	68	0	0	+	14	N.R.
T3	24 Nov 82	59	0	0	0	9	N.R.
-Patient F, male, age 27							
Tooth #5:							
T1	4 Oct 82	29	++	+	+	24	44
T2	11 Oct 82	36	0	0	+	19	54
T3	29 Nov 82	39	0	0	0	9	59
Tooth #12:							
T1	4 Oct 82	34	+++	++	+++	24	44
T2	11 Oct 82	33	0	0	+	9	54
T3	29 Nov 82	42	0	0	0	4	54
Tooth #21:							
T1	11 Oct 82	35	++	++	+++	24	44
T2	18 Oct 82	35	0	0	0	N.R.	N.R.
T3	29 Nov 82	34	0	0	0	N.R.	59

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient G, male, age 50							
Tooth #3:							
T1	4 Oct 82	29	+++	+	++	24	44
T2	11 Oct 82	23	++	0	+	24	49
T3	16 Dec 82	25	0	0	+	14	54
Tooth #7:							
T1	4 Oct 82	19	++	+	+	29	44
T2	11 Oct 82	20	0	0	+	19	49
T3	16 Dec 82	11	0	0	0	9	59
Tooth #10:							
T1	4 Oct 82	9	++	+	++	24	39
T2	11 Oct 82	3	0	0	+	9	49
T3	16 Dec 82	17	0	0	0	4	59
-Patient H, male, age 69							
Tooth #11:							
T1	11 Oct 82	N.R.*	+	++	+	24	54
T2	18 Oct 82	N.R.*	0	+	0	29	44
T3	6 Dec 82	N.R.*	0	+	0	19	44

* No response to pulp testing

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient H							
Tooth #27:							
T1	18 Oct 82	22	++	++	+++	29	44
T2	25 Oct 82	20	+	+	++	24	49
T3	6 Dec 82	28	0	++	++	24	44
-Patient I, male, age 25							
Tooth #4:							
T1	13 Oct 82	35	+	0	++	24	44
T2	20 Oct 82	41	0	0	0	14	N.R.
T3	8 Dec 82	35	0	0	0	9	N.R.
Tooth #5:							
T1	13 Oct 82	30	+	0	+	19	49
T2	20 Oct 82	38	0	0	0	14	N.R.
T3	8 Dec 82	40	0	0	0	9	N.R.
-Patient J, female, age 29							
Tooth #14:							
T1	22 Oct 82	29	++	0	+++	19	49
T2	29 Oct 82	38	+	0	++	19	49
T3	10 Dec 82	31	++	0	++	24	49

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient K, male, age 64							
Tooth #13:							
T1	25 Oct 82	36	++	0	+++	29	44
T2	1 Nov 82	42	+	0	+	29	44
T3	13 Dec 82	35	+	0	++	19	44
-Patient L, female, age 70							
Tooth #24:							
T1	3 Nov 82	2	+++	++	+	19	49
T2	8 Nov 82	5	0	+	0	14	54
T3	5 Jan 83	6	+	+	0	19	49
Tooth #25:							
T1	3 Nov 82	2	+	+	+	19	44
T2	8 Nov 82	7	0	+	+	14	54
T3	5 Jan 83	7	+	+	+	14	49
Tooth #26:							
T1	3 Nov 82	12	+	+	+	14	44
T2	8 Nov 82	19	0	+	+	9	49
T3	5 Jan 83	18	+	+	0	14	54

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient M, male, age 61							
Tooth #4:							
T1	3 Nov 82	20	+	+	+	24	44
T2	10 Nov 82	31	+	+	+	14	49
T3	5 Jan 83	26	0	0	0	N.R.	N.R.
Tooth #5:							
T1	3 Nov 82	15	+	0	0	24	44
T2	10 Nov 82	19	+	+	0	24	49
T3	5 Jan 83	16	0	0	0	N.R.	N.R.
-Patient N, female, age 34							
Tooth #5:							
T1	15 Nov 82	19	++	+	+	24	39
T2	22 Nov 82	9	0	0	+	24	39
T3	7 Jan 83	12	+	+	++	19	39
Tooth #11:							
T1	15 Nov 82	12	++	+	+	24	39
T2	22 Nov 82	32	0	+	+	19	39
T3	7 Jan 83	13	+	+	++	19	39

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient N							
Tooth #12:							
T1	15 Nov 82	6	++	++	+	24	39
T2	22 Nov 82	11	0	0	+	19	39
T3	7 Jan 83	16	+	+	++	19	39
-Patient O, male, age 29							
Tooth #12:							
T1	29 Nov 82	45	+	0	+	19	49
T2	6 Dec 82	40	0	0	+	9	59
T3	17 Jan 83	41	0	0	+	9	54
-Patient P, female, age 42							
Tooth #8:							
T1	6 Dec 82	19	++	++	++	29	39
T2	14 Dec 82	18	0	0	+	19	54
T3	21 Jan 83	18	0	0	+	9	54

	Date	P.T.	O.R.	T.R.	A.S.R.	Cold	Warm
-Patient P							
Tooth #9:							
T1	6 Dec 82	14	++	+	+++	19	44
T2	14 Dec 82	30	0	0	+	14	49
T3	21 Jan 83	28	0	0	0	4	N.R.

END

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